



PATENT CASE CV06038US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
**Duane A. Burnett et al.**

For:  
**Substituted Azetidinone Compounds,  
Processes for Preparing the Same,  
Formulations and Uses Thereof**

Serial No.: **10/792,346**

Filed: **03/03/2004**

X  
: Examiner: To Be Assigned  
: Group Art Unit: 1614  
: Date: September 23, 2004  
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:  
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X

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants respectfully request that the following be considered and made record, as well as the documents listed on the accompanying PTO Form 1449.

A research study was initiated on April 17, 1997 in the United States in which patients were administered capsules of the formulations of Exhibits A, B or C. Copies of the formulation Exhibits A, B and C and the informed consent form for the study (Exhibit 1) are submitted herewith for the Examiner's consideration.

A research study was initiated on October 21, 1997 in the United States in which patients were administered tablets of the formulations of Exhibits D or E or capsules of formulation of Exhibit C. Copies of the formulation Exhibits C, D and E and the informed consent for the study (Exhibit 2) are submitted herewith for the Examiner's consideration.

A research study was initiated on November 5, 1998 in the United States in which patients were administered tablets of formulations of Exhibits D, F, G or H. Copies of the formulation Exhibits D, F, G and H and the informed consent for the study (Exhibit 3) are submitted herewith for the Examiner's consideration.

A research study was initiated on April 20, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D, optionally in coadministration with digoxin. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 4) are submitted herewith for the Examiner's consideration.

A research study was initiated on August 27, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D optionally in coadministration with Gemfibrozil 600mg tablets. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 5) are submitted herewith for the Examiner's consideration.

In the Informed Consents accompanying the above research studies, Schering's active pharmaceutical ingredient, i.e., ezetimibe, was identified as "SCH 58235" and as an "experimental drug which inhibits the absorption of cholesterol". It was not identified by its chemical name, generic name or by its chemical formula.

The Commissioner is authorized to charge Deposit Account No. 19-0365 for any additional fees deemed necessary for consideration and entry of this Information Disclosure Statement into the file record.

Pursuant to Rule 56, it is requested that the documents listed on the accompanying PTO-1449 Form be considered and made of record in the above-identified patent application. Copy(ies) of these references  are attached  were filed in related application U.S. Serial No(s) \_\_\_\_\_ filed \_\_\_\_\_, respectively.

(b) No fee is believed due because:

- This Information Disclosure Statement is being filed within three (3) months of the filing date of the application.
- This Information Disclosure Statement is being concurrently filed with the above-identified application.
- This Information Disclosure Statement is being concurrently filed with a Request for Continued Examination (RCE).
- This Information Disclosure Statement is being filed prior to the mailing of a first Office Action on the merits.

(c)  This Information Disclosure Statement is being filed before the mailing date of any final action, notice of allowance or an action that otherwise closes prosecution; and

- Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; or
- The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.

(d)  This Information Disclosure Statement is being filed on or before the payment of the issue fee; and

- Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and
- The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.

The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 19-0395, Patent Case No. CV06038US01.

Respectfully submitted,  
SCHERING-PLOUGH CORPORATION

Dated: **September 23, 2004**  
SCHERING-PLOUGH CORPORATION  
Patent Department, K-6-1, 1990  
2000 Galloping Hill Road  
Kenilworth, NJ 07033-0530  
Facsimile No.: (908) 298-5388

By:

  
Name: **Ann M. Cannon**  
Reg. No.: **35,972**  
**Attorney of Record**  
Telephone No.: (908) 298-5024

O I P E  
SEP 27 2004Sheet 1 of 15

FORM PTO9449 TRADE MARKS		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: <b>CV6038US01</b>	APPLICATION NO.: <b>10/792,346</b>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i>		APPLICANT: <b>Duane A. Burnett et al.</b>				
		FILING DATE: <b>03/03/2004</b>		GROUP: <b>1614</b>		
FOREIGN PATENT DOCUMENTS						
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES      NO
AA	BE 884722 A	12/01/80	BELGIUM	C07D	AG1K	X(abs.)
AB	CA 2253769	11/29/99	CANADA	A61K	31/22	
AC	DE 2046823 A	03/30/72	GERMANY	C07C		X(abs.)
AD	DE 2521113 A	03/18/76	GERMANY	C07C	87/34	X(abs.)
AE	EP 0002151 A1,B1	05/30/79	EUROPE	C07C	69/67	
AF	EP 0010299 B1	02/15/84	EUROPE	A61K	45/06	
AG	EP 0179559 A2	04/30/86	EUROPE	C07D	405/06	
AH	EP 0199630 A1	10/29/86	EUROPE	C07D	205/08	
AI	EP 0199630 B1	09/19/90	EUROPE	C07D	205/08	
AJ	EP 0264231 A1	04/20/88	EUROPE	C07D	205/08	
AK	EP 0266896 B1	05/11/88	EUROPE	C07D	471/04	
AL	EP 0274873 B1	07/20/88	EUROPE	C07K	11/00	
AM	EP 0288973 B1	11/02/88	EUROPE	C07D	417/06	
AN	EP 0311366 B1	04/12/89	EUROPE	C07D	471/04	
AO	EP 0333268 A1	09/20/89	EUROPE	C07F	7/18	
AP	EP 0337549 A1	10/18/89	EUROPE	C07D	205/08	
AQ	EP 0337549 B1	10/04/95	EUROPE	C07D	205/08	
AR	EP 0365364 A2	04/25/90	EUROPE	C07D	205/08	
AS	EP 0369686 A1	05/23/90	EUROPE	C07D	463/00	
AT	EP 0375527 A1	06/27/90	EUROPE	C07D	205/08	X(abs.)
AU	EP 0401705 A3	12/12/90	EUROPE	A61K	31/66	
AV	EP 0415487 A2	03/06/91	EUROPE	C07D	205/08	
AW	EP 0455042 A1	11/06/91	EUROPE	A61K	31/19	
AX	EP 0457514 A1	11/21/91	EUROPE	A61K	45/06	
AY	EP 0457514 B1	08/21/96	EUROPE	A61K	45/06	
AZ	EP 0461548 A3	12/18/91	EUROPE	A61K	31/365	
BA	EP 0462667 A2	12/27/91	EUROPE	C07D	205/08	
BB	EP 0475148 A1	03/18/92	EUROPE	A61K	31/215	
BC	EP 0475755 B1	03/18/92	EUROPE	C07D	403/06	
BD	EP 0481671 A1	04/22/92	EUROPE	C07D	205/08	
BE	EP 0482498 A3	04/29/92	EUROPE	A61K	31/66	
BF	EP 0524595 A1	01/27/93	EUROPE	C07D	205/08	
BG	EP 0720599 B1	07/10/96	EUROPE	C07D	205/08	
BH	EP 0793958 A2	09/10/97	EUROPE	A61K	9/16	X(abs)
BI	EP 0814080 A1	12/29/97	EUROPE	C07D	267/14	
BJ	EP 0904781 A2	03/31/99	EUROPE	A61K	31/215	
BK	EP 1048295 A2	11/02/00	EUROPE	A61K	31/216	
BL	FR 1103113	10/31/55	FRANCE			X
BM	FR 2779347	12/10/97	FRANCE	A61	31/215	X(abs.)
BN	GB 861367	02/22/61	GB	A61K		
BO	GB 902658	08/09/62	GB	C07D		
BP	GB 1415295	11/26/75	GB	C07C	59/26	

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**FOREIGN PATENT DOCUMENTS**

BQ	GB 2329334 A	03/24/99	GB	A61K	45/00	
BR	JP 028057	10/01/81	JAPAN			X(abs.)
BS	JP 121479	12/10/86	JAPAN			X(abs.)
BT	JP 136485	05/26/81	JAPAN			X(abs.)
BU	JP 180212	03/24/86	JAPAN			X(abs.)
BV	JP 219681	04/14/87	JAPAN			X(abs.)
BW	JP 5194209 A	08/03/93	JAPAN	A61K	031/22	X(abs.)
BX	JP 5239020 A	1993	JAPAN	C07D	205/08	X(abs.)
BY	JP 4054182 A	1992	JAPAN	C12P	017/16	X(abs.)
BZ	JP 63017859 A	1988	JAPAN	C07D	205/08	X(abs.)
CA	JP 4266869 A	1992	JAPAN	C07D	205/08	X(abs.)
CB	JP 4356195 A	1993	JAPAN			X(abs.)
CC	JP 4356495	12/10/92	JAPAN			X(abs.)
CD	JP 5058993 A	1993	JAPAN			X(abs.)
CE	JP 61280295 A	1987	JAPAN			X(abs.)
CF	JP 95051558 B2	06/05/95	JAPAN	C07D	205/08	X(abs.)
CG	JP 91068020	10/25/91	JAPAN	C07D	205/08	X(abs.)
CH	JP 94047573	06/22/94	JAPAN	C07D	205/08	X(abs.)
CI	WO 82/01649	05/27/82	PCT	A61K	9/52	X(abs.)
CJ	WO 87/04429	07/30/87	PCT	C07D	205/08	
CK	WO 88/04656	06/30/88	PCT	C07D	405/04	
CL	WO 88/05296	07/28/88	PCT	A61K	31/365	
CM	WO 91/03249	03/21/91	PCT	A61K	31/785	X(abs.)
CN	WO 92/13837	08/20/92	PCT	C07D	205/08	
CO	WO 93/02048	02/04/93	PCT	C07D	205/08	
CP	WO 93/07167	04/15/93	PCT	C07J	71/00	
CQ	WO 93/11150	06/10/93	PCT	C07J	71/00	
CR	WO 94/00480	01/06/94	PCT	C07J	71/00	
CS	WO 94/14433	07/07/94	PCT	A61K	31/395	
CT	WO 94/17038	08/04/94	PCT	C07D	205/12	
CU	WO 94/20535	09/15/94	PCT	C07K	13/00	
CV	WO 95/04533	02/16/95	PCT	A61K	31/445	
CW	WO 95/06470	03/09/95	PCT	A61K	31/435	
CX	WO 95/08532	03/30/95	PCT	C07D	205/08	
CY	WO 95/18143	07/6/95	PCT	C07J	71/00	
CZ	WO 95/26334	10/05/95	PCT	C07D	205/08	
DA	WO 95/28919	11/02/95	PCT	A61K	31/19	X(abs.)
DB	WO 95/35277	12/28/95	PCT	C07D	205/08	
DC	WO 96/00288	01/04/96	PCT	C12N	15/12	
DD	WO 96/09827	04/04/96	PCT	A61K	31/58	
DE	WO 96/16037	05/30/96	PCT	C07D	205/08	

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: <b>CV06038US01</b>	APPLICATION NO.: <b>10/792,346</b>
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**FOREIGN PATENT DOCUMENTS**

	DF	WO96/19450	06/27/96	PCT	C07D	205/08		
	DG	WO 96/19987	07/04/96	PCT	A61K	31/35		
	DH	WO 96/40255	12/19/96	PCT	A61K	45/06		
	DI	WO 97/16455	05/09/97	PCT	C07H	3/04		
	DJ	WO 97/18304	05/22/97	PCT	C12N	15/00		
	DK	WO 97/25042	07/17/97	PCT	A61K	31/42		
	DL	WO 97/28149	08/07/97	PCT	C07D	307/79		
	DM	WO 97/31907	09/04/97	PCT	C07D	263/56		
	DN	WO 97/35576	10/02/97	PCT	A61K	31/44		
	DO	WO 97/46238	12/11/97	PCT	A61K	31/245		
	DP	WO 98/01100	01/15/98	PCT	A61K			
	DQ	WO 98/05331	02/12/98	PCT	A61K	31/45		
	DR	WO 98/14179	04/09/98	PCT	A61K	9/50		
	DS	WO 98/31360	07/23/98	PCT	A61K	31/19		
	DT	WO 98/31361	07/23/98	PCT	A61K	31/215	X(abs.)	
	DU	WO 98/31366	07/23/98	PCT	A61K	31/445		
	DV	WO 98/43081	10/01/98	PCT	G01N	33/50		
	DW	WO 98/46215	10/22/98	PCT	A61K	9/20		
	DX	WO 98/47518	10/29/98	PCT	A61K	31/715		
	DY	WO 98/57652	12/23/98	PCT	A61K	31/785		
	DZ	WO 99/04815	04/02/99	PCT	A61K	45/00	X(abs.)	
	EA	WO 99/06035	02/11/99	PCT	A61K	31/00		
	EB	WO 99/06046	02/11/99	PCT	A61K	31/455		
	EC	WO 99/08501	2/25/99	PCT				
	ED	WO 99/09967	03/04/99	PCT	A61K	31/00		
	EE	WO 99/12534	03/18/99	PCT	A61K	31/17	X(abs.)	
	EF	WO 99/11260	03/11/99	PCT	A61K	31/40		
	EG	WO 99/15159	04/01/99	PCT	A61K	31/00		
	EH	WO 99/15520	04/01/99	PCT	C07D	319/20	X(abs.)	
	EI	WO 99/18072	04/15/99	PCT	C07D	205/08		
	EJ	WO 99/20275	04/29/99	PCT	A61K	31/47		
	EK	WO 99/20614	04/29/99	PCT	C07D	265/36		
	EL	WO 99/29300	06/17/99	PCT	A61K	9/107		
	EM	WO 99/38498	08/05/99	PCT	A61K	31/00		
	EN	WO 99/38845	08/05/99	PCT	C07D	213/65		
	EO	WO 99/38850	08/05/99	PCT	C07D	237/32		
	EP	WO 99/46232	09/16/99	PCT	C07C	62/34	X(abs.)	
	EQ	WO 99/47123	09/23/99	PCT	A61K	9/16		
	ER	WO 99/48488	09/30/99	PCT	A61K	31/00		
	ES	WO 99/66929	12/29/99	PCT	A61K	31/405		

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**FOREIGN PATENT DOCUMENTS**

	ET	WO 99/66930	12/29/99	PCT	A61K	31/405		
	EU	WO 00/04011	01/27/00	PCT	C07D	319/06		
	EV	WO 00/07617	02/17/00	PCT	A61K	38/26		
	EW	WO 00/16749	03/30/00	PCT	A61K	9/16	X(abs.)	
	EX	WO 97/21676	06/19/97	PCT	C07D	205/09		
	EY	WO 97/41098	11/06/97	PCT	C07D	205/09		
	EZ	WO 00/18395	04/06/00	PCT	A61K	31/215		
	FA	WO 00/20623	04/13/00	PCT	C12P	41/00		
	FB	WO 00/23415	04/27/00	PCT	C07C	69/734		
	FC	WO 00/23416	04/27/00	PCT	C07C	69/734		
	FD	WO 00/23425	04/27/00	PCT	C07D	209/80		
	FE	WO 00/23445	04/27/00	PCT	C07D	471/12		
	FF	WO 00/23451	04/27/00	PCT	C07D	487/14		
	FG	WO 00/28981	05/25/00	PCT	A61K	31/00		
	FH	WO 00/31548	06/02/00	PCT	G01N	33/68		
	FI	WO 00/32189	06/08/00	PCT	A61K	31/415		
	FJ	WO 00/34240	06/15/00	PCT	C07D	205/08		
	FK	WO 00/37057	06/29/00	PCT	A61K	9/48		
	FL	WO 00/37078	06/29/00	PCT	A61K	31/44	X(abs.)	
	FM	WO 00/38721	07/06/00	PCT	A61K	45/06		
	FN	WO 00/38722	07/06/00	PCT	A61K	45/06		
	FO	WO 00/38723	07/06/00	PCT	A61K	45/06		
	FP	WO 00/38724	07/06/00	PCT	A61K	45/06		
	FQ	WO 00/38725	07/06/00	PCT	A61K	45/06		
	FR	WO 00/38726	07/06/00	PCT	A61K	45/06		
	FS	WO 00/38727	07/06/00	PCT	A61K	45/06		
	FT	WO 00/38728	07/06/00	PCT	A61K	45/06		
	FU	WO 00/38729	07/06/00	PCT	A61K	45/06		
	FV	WO 00/40247	07/13/00	PCT	C07D	265/26		
	FW	WO 00/45817	08/10/00	PCT	A61K	31/505		
	FX	WO 00/50392	08/31/00	PCT	C07C	323/52	X(abs.)	
	FY	WO 00/53149	09/14/00	PCT	A61K			
	FZ	WO 00/53173	09/14/00	PCT	A61K	31/22		
	GA	WO 00/53563	09/14/00	PCT	C07C	59/92	X(abs.)	
	GB	WO 00/56403	09/28/00	PCT	A61P	9/10		
	GC	WO 00/57859	10/05/00	PCT	A61K	9/48		
	GD	WO 00/57918	10/05/00	PCT	A61K	47/44		
	GE	WO 00/60107	10/12/00	PCT	C12P	17/10		
	GF	WO 00/63153	10/26/00	PCT	C07C	69/734		
	GG	WO 00/63161	10/26/00	PCT	C07C	237/30		

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<b>FOREIGN PATENT DOCUMENTS</b>					
GH	WO 00/63190	10/26/00	PCT	C07D	265/38
GI	WO 00/63196	10/26/00	PCT	C07D	277/04
GJ	WO 00/63209	10/26/00	PCT	C07D	471/04
GK	WO 00/63703	10/26/00	PCT	G01N	33/92
GL	WO 00/69412	11/23/00	PCT	A61K	9/127
GM	WO 00/69445	11/23/00	PCT	A61K	31/785
GN	WO 00/72825	12/7/00	PCT	A61K	9/14
GO	WO 00/72829	12/07/00	PCT	A61K	9/48
GP	WO 00/75103	12/14/00	PCT	C07C	235/60
GQ	WO 00/76482	12/21/00	PCT	A61K	9/48
GR	WO 00/76488	12/21/00	PCT	A61K	31/00
GS	WO 00/78312	12/28/00	PCT	A61K	31/421
GT	WO 00/78313	12/28/00	PCT	A61K	31/422
GU	WO 01/00579	01/04/01	PCT	C07D	213/65
GV	WO 01/00603	01/04/01	PCT	C07D	277/24
GW	WO 01/08686	02/08/01	PCT	A61K	31/495
GX	WO 01/12176	02/22/01	PCT	A61K	31/16
GY	WO 01/12187	02/22/01	PCT	A61K	31/404
GZ	WO 01/12612	02/22/01	PCT	C07D	257/04
HA	WO 01/14349	03/01/01	PCT	C07D	277/34
HB	WO 01/14350	03/01/01	PCT	C07D	277/34
HC	WO 01/14351	03/01/01	PCT	C07D	277/34
HD	WO 01/15744	03/08/01	PCT	A61K	49/00
HE	WO 01/16120	03/08/01	PCT	C07D	263/32
HF	WO 01/17994	03/15/01	PCT	C07D	413/12
HG	WO 01/18210	03/15/01	PCT	C12N	15/12
HH	WO 01/21181	03/29/01	PCT	A61K	31/675
HI	WO 01/21259	03/29/01	PCT	A61P	
HJ	WO 01/21578	03/29/01	PCT	C07C	235/60
HK	WO 01/21647	03/29/01	PCT	C07K	14/00
HL	WO 01/22962	04/05/01	PCT	A61K	31/435
HM	WO 01/25225	04/12/01	PCT	C07D	317/18
HN	WO 01/25226	04/12/01	PCT	C07D	327/04
HO	WO 01/30343	05/03/01	PCT	A61K	31/40
HP	WO 01/32161	05/10/01	PCT	A61K	31/00
HQ	WO 01/35970	05/25/01	PCT	A61K	35/76
HR	WO 01/40192	06/07/01	PCT	C07D	217/26
					X(abs.)

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**FOREIGN PATENT DOCUMENTS**

	HS	WO 01/45676	06/28/01	PCT	A61K	9/24		
	HT	WO 01/49267	07/12/01	PCT	A61K	9/14		
	HU	WO 01/64221	09/07/01	PCT	A61K	31/52		
	HV	WO 01/76632	10/18/01	PCT	A61K	45/06		
	HW	WO 02/50090	06/27/02	PCT	C07H	15/26		
	HX	WO 02/058696	08/01/02	PCT	A61K	31/397		
	HY	WO 02/058731	08/01/02	PCT	A61K	45/06		
	HZ	WO 02/058732	08/01/02	PCT	A61K	45/06		
	IA	WO 02/058733	08/01/02	PCT	A61K	45/06		
	IB	WO 02/058734	08/01/02	PCT	A61K	45/06		
	IC	WO 02/058685	08/01/02	PCT	A61K	31/00		
	ID	WO 02/064130	08/22/02	PCT	A61K	31/195		
	IE	WO 02/064549	08/22/02	PCT	C07C	275/34		
	IF	WO 02/064664	08/22/02	PCT	C08G	77/02		
	IG	WO 02/072104	09/19/02	PCT	A61K	31/54		
	IH	WO 02/081454	10/17/02	PCT	C07D	239/36		
	II	WO 02/26729	04/04/02	PCT	C07D	311/66		
	IJ	WO 02/064094	08/22/02	PCT	A61K			
	IK	WO 02/50027	06/27/02	PCT				
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	IO	EP 1 036 563 A1	09/20/00	EPO				
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	IS	WO 02/08188	01/31/02	PCT				
	IT	WO 03/039542	05/15/03	PCT				
	IU	WO 03/074101	09/12/03	PCT				
	IV	WO 03/088962	10/30/03	PCT				
	IW	WO 03/018024	03/06/03	PCT	A61K	31/55		
	IX	WO 03/018059	03/06/03	PCT	A61K	45/06		

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IY	<b>Exhibit A:</b> SCH 58235 Micronized (ezetimibe), Drug Formulation Development Summary		
IZ	<b>Exhibit B:</b> SCH 58235 (ezetimibe), Drug Formulation Development Summary		
JA	<b>Exhibit C:</b> SCH 58235 (ezetimibe), Drug Formulation Development Summary		
JB	<b>Exhibit D:</b> SCH 58235 (ezetimibe), Drug Formulation Development Summary		
JC	<b>Exhibit E:</b> SCH 58235 (ezetimibe), Drug Formulation Development Summary		
JD	<b>Exhibit F:</b> SCH 58235 (ezetimibe), Drug Formulation Development Summary		
JE	<b>Exhibit G:</b> SCH 58235 (ezetimibe), Drug Formulation Development Summary		
JF	<b>Exhibit H:</b> SCH 58235 (ezetimibe), Drug Formulation Development Summary		
JG	<b>Exhibit 1:</b> Master Sheet for the SCH 58235 and Lovastatin Research Study, <i>Schering-Plough Research Institute</i> (Protocol No. C906-411), page 1576-1585		
JH	<b>Exhibit 2:</b> Medical Research Study #1055/97, SCH 58235: Bioavailability of Single Oral Doses of Two Prototype Tablet Formulations and the Reference Capsule Formulation of SCH 58235 in Normal Male Volunteers: A Four Way Crossover Study #C97-221-01, Informed Consent, <i>Peninsular Testing Corporation</i> , page 106-112		
JI	<b>Exhibit 3:</b> Consent Form to Participate in a Research Study, "A Phase II Double Blind Dose Response Investigation of Efficacy and Safety of Four Doses of SCH 58235 Compared to Placebo in Subjects with Primary Hypercholesterolemia," <i>Schering-Plough Research Institute</i> (Protocol No. C98-010), page 1558-1566		
JJ	<b>Exhibit 4:</b> Medical Research Study #1096/99, SCH 58235: Pharmacokinetic Pharmacodynamic Drug Interaction Study with Digoxin in Healthy Volunteers #C98-114, Informed Consent, <i>Peninsular Testing Corporation</i> , page 124-130		
JK	<b>Exhibit 5:</b> Informed Consent, "SCH 58235: Assessment of Multiple-Dose Drug Interaction Between 58235 and Gemfibrozil in Healthy Volunteers," <i>Schering-Plough Research Institute</i> , page 1-8		
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